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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,967	02/23/2004	James Oliver Dolly	17790(BOT)	6222

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EXAMINER	
ARCHIE, NINA	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,967	DOLLY ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,50,53-55,57-62,69,70,73 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,50,53-55,57-62,69,70,73 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/31/2002, 7/15/2002, 5/21/2002.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

3. The information disclosure statement filed on 12/31/2002, 7/15/2002, and 5/21/2002 have been considered. Initialed copies are enclosed.

Election/Restrictions

4. Applicant's election of Group I, claims 48, 50, 53-55, 57-62, 69-70, 73, and 75 in the response filed 2-12-07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Group II (claims 49, 51-76, and 78-85), Group III (claims 89-93 and 102) and Group IV (claims 94-103) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 2-12-07.

Claim Objections

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification refers to "N-acetyl-CRATKML-carboxamide" (see pg. 4 lines 4-10 and pg. 18 lines 10-15). Claim 75; recite the limitation "N-acetyl-CRATML-carcoximide".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim recites the inhibitor ("N-acetyl-CRATML-carcoximide"). This laboratory nomenclature is not provided for in the specification as originally filed. There is no N-acetyl-CRATML-carcoximide provided from in the written description of the specification. Therefore, it is apparent, that Applicants were not in possession of the claimed inhibitor at the time of filing. The description of inhibitor "N-acetyl-CRATML-carcoximide" does not support an abbreviated nomenclature. Applicants pointing to the specification by page and line number where specific written description for the inhibitor N-acetyl-CRATML-carcoximide and sequence thereof can be found best resolve this issue.

6. Claims 48, 50, 53-55, 57-62, 69-70, 73, and 75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 48 and 50 independent claims and all dependent claims 53-55, 57-62, 69-70, 73, and 75 are drawn to a method of treating and preventing poisoning by a clostridial toxin in a patient in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 to the patient, wherein the toxin-resistant SNAP-25 is a SNAP-25 resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 is a SNAP-25 capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning. The specification discloses that SNAP-25 is a variant and can include insertions, deletions and substitutions, either conservative or non-conservative (see specification pg. 19 lines 15-27) thus that the replacement residue can be replaced with any amino acid residue. The specification does not teach any structural limitations of SNAP-25. Therefore, the specification lacks written description of the claimed method of treating and preventing poisoning by a clostridial toxin in a patient in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 to the patient. This issue is best resolved by Applicants pointing to the specification by page and line number where description of the claimed invention is set forth.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 48, 50, 53-55, 57-62 and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Carroll et al US Patent No. 5,599,539 Date February 4, 1997.

Claims 48, 50, 53-55, 57-62 and 69-70 are drawn to a method of treating and preventing poisoning by a clostridial toxin in a patient in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 to the patient, wherein the toxin-resistant SNAP-25 is a SNAP-25 resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 is a SNAP-25 capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning.

Carroll et al teach a method of treating and preventing poisoning by a clostridial toxin in a patient (infant and adult) in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 (antitoxin) or a toxin-inhibitory SNAP-25 (antitoxin) to the patient and thus this limitation of antitoxin correlates with the teachings of the specification of SNAP-25 (i.e. any protein) (see specification pg. 19 lines 15-27). Carroll et al teach that a toxin-resistant SNAP-25 (antitoxin) inherently is a SNAP-25 resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 is a SNAP-25 capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning, wherein the clostridial toxin is a botulinum toxin type A, wherein the clostridial toxin is botulinum toxin type C1, wherein the clostridial toxin is

botulinum toxin type E, wherein the clostridial toxin poisoning is botulism (see abstract, column 3 lines 25-67, column lines 1-10 lines 24-57, column 5 lines 61-67, column 7 lines 9-31 see claims columns 21-22).

As to dependent claims 57-61, the method of Carroll et al would inherently teach a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 comprising a replacement of a residue equivalent to residue 197 of full length SNAP-25 by a residue other than Q, a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 comprising a replacement of a residue equivalent to residue 198 of full length SNAP-25 by a residue other than R, wherein a residue equivalent to residue Q197 of full length SNAP-25 is replaced, by a residue selected from the group consisting of A, K and W, wherein the residue equivalent to R198 of full length human SNAP-25 is replaced by a residue selected from the group consisting of A, T, K, H and W. Carroll et al would inherently teach a toxin-resistant SNAP-25 capable of performing substantially the equivalent function of a SNAP-25 endogenously present in a patient because SNAP-25 is a variant as described in the specification with insertions, deletions and substitutions and would also inherently be capable of performing substantially the equivalent function of a SNAP-25 in the absence of evidenced to the contrary (see specification pg. 19 lines 15-27).

Claims 48, 50, 53, 57-62 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Siegel et al 1988 Journal of Clinical Microbiology Vol. 26 No. 11 pgs. 2351-2356.

Claims 48, 50, 53, 57-62 and 70 are drawn to a method of treating and preventing poisoning by a clostridial toxin in a patient in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 to the patient, wherein the toxin-resistant SNAP-25 is a SNAP-25 resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 is a SNAP-25 capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning.

Siegel et al teach a method of treating and preventing (at risk) poisoning by a clostridial toxin in a patient (i.e. adult/laboratory personnel) in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 (Botulinum pentavalent ABCDE) or a toxin-inhibitory SNAP-25 (Botulinum pentavalent ABCDE) to the patient and thus this limitation of Botulinum pentavalent correlates with the teachings of the specification of SNAP-25 (i.e. any protein) (see specification pg. 19 lines 15-27). Siegel et al teach that a toxin-resistant SNAP-25 (Botulinum pentavalent ABCDE) inherently is a SNAP-25 (Botulinum pentavalent ABCDE) resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 (Botulinum pentavalent ABCDE) is a SNAP-25 (Botulinum pentavalent ABCDE) capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 (Botulinum pentavalent ABCDE) produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning, wherein the clostridial toxin is a botulinum toxin type A, wherein the clostridial toxin poisoning is botulism (see abstract, pg. 2351, pgs. 2352 Material and Methods, column 2 last paragraph, pg. 2354 Table 3 and Discussion).

As to dependent claims 57-61, the method of Siegel et al would inherently teach a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 comprising a replacement of a residue equivalent to residue 197 of full length SNAP-25 by a residue other than Q, a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 comprising a replacement of a residue equivalent to residue 198 of full length SNAP-25 by a residue other than R, wherein a residue equivalent to residue Q197 of full length SNAP-25 is replaced, by a residue selected from the group consisting of A, K and W, wherein the residue equivalent to R198 of full length human SNAP-25 is replaced by a residue selected from the group consisting of A, T, K, H and W. Siegel et al would inherently teach a toxin-resistant SNAP-25 capable of performing substantially the equivalent function of a SNAP-25 endogenously present in a patient because SNAP-25 is a variant as described in the specification with insertions, deletions and substitutions and would also

inherently be capable of performing substantially the equivalent function of a SNAP-25 in the absence of evidenced to the contrary (see specification pg. 19 lines 15-27).

Claims 48, 53, 57-62 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Roland et al 1986 CMAJ, Vol. 135 pgs. 130-131.

Claims 48, 53, 57-62 and 69 are drawn to a method of treating and preventing poisoning by a clostridial toxin in a patient in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 to the patient, wherein the toxin-resistant SNAP-25 is a SNAP-25 resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 is a SNAP-25 capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning.

Roland et al teach a method of treating poisoning by a clostridial toxin in a patient (infant) in need thereof, the method comprising the step of administering an effective amount of a toxin-resistant SNAP-25 (ampicillin) or a toxin-inhibitory SNAP-25 (ampicillin) to the patient and thus this limitation of ampicillin correlates with the teachings of the specification of SNAP-25 (i.e. any protein) (see specification pg. 19 lines 15-27). Roland et al teach that a toxin-resistant SNAP-25 (ampicillin) inherently is a SNAP-25 resistant to proteolysis by the clostridial toxin, wherein the toxin-inhibitory SNAP-25 (ampicillin) is a SNAP-25 (ampicillin) capable of inhibiting the protease activity of the clostridial toxin, wherein administration of the toxin-resistant SNAP-25 or the toxin-inhibitory SNAP-25 (ampicillin) produces a clinically useful or significant reduction in a symptom of poisoning caused by the clostridial toxin in the patient suffering from clostridial toxin poisoning, wherein the clostridial toxin is a botulinum toxin type A, wherein the clostridial toxin poisoning is botulism (see Case Report).

As to dependent claims 57-61, the method of Roland et al would inherently teach a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 comprising a replacement of a residue equivalent to residue 197 of full length SNAP-25 by a residue other than Q, a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 comprising a replacement of a residue equivalent to residue 198 of full length SNAP-25 by a residue other than R, wherein a residue equivalent to residue Q197 of full length SNAP-25 is replaced, by a residue selected from the group consisting of A, K and W, wherein the residue equivalent to R198 of full length human SNAP-25 is replaced by a residue selected from the group consisting of A, T, K, H and W. Carroll et al would inherently teach a toxin-resistant SNAP-25 capable of performing substantially the equivalent function of a SNAP-25 endogenously present in a patient because SNAP-25 is a variant as described in the specification with insertions, deletions and substitutions and would also inherently be capable of performing substantially the equivalent function of a SNAP-25 in the absence of evidenced to the contrary (see specification pg. 19 lines 15-27).

Status of the Claims

6. No claims are allowed.

Claims 48, 50, 53-55, 57-62, 69-70, 73, and 75 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER